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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/891,715 06/26/2001 Richard L. Mueller 5756-0013.30 1828

7590 07/22/2003

PENNIE &EDMONDS LLP 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036 EXAMINER
RODRIGUEZ, CRIS LOIREN

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

1		
	Application No.	Applicant(s)
Office Action Summary	09/891,715	MUELLER ET AL.
	Examiner	Art Unit
	Cris L. Rodriguez	3763
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICAT  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communica  - If the period for reply specified above is less than thirty (30) day  - If NO period for reply is specified above, the maximum statutory  - Failure to reply within the set or extended period for reply will, b  - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).  Status	FION.  CFR 1.136(a). In no event, however, may a tion.  s, a reply within the statutory minimum of thir y period will apply and will expire SIX (6) MON by statute, cause the application to become Al	reply be timely filed  rly (30) days will be considered timely.  NTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133).
1) Responsive to communication(s) filed on <u>12 May 2003</u> .		
2a) This action is FINAL. 2b)	☐ This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims	under <i>Ex parte Quayle</i> , 1933 C.	D. 11, 400 O.G. 215.
4)⊠ Claim(s) <u>1-21</u> is/are pending in the application.		
4a) Of the above claim(s) 2-4,7-9,13-16 and 19-21 is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1,5,6,10-12,17 and 18</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers  ONT The energification is chicated to by the Evaminer		
9)⊠ The specification is objected to by the Examiner.  10)□ The drawing(s) filed on is/are: a)□ accepted or b)□ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) ☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
<ul> <li>a)           The translation of the foreign language provisional application has been received.     </li> <li>15)           Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.     </li> </ul>		
Attachment(s)		
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-93)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper</li> </ol>	(48) 5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152)

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#### **DETAILED ACTION**

### Election/Restrictions

- 1. Applicant's election of Group I, claims 1-18, in paper No. 6, and further election of Species I and a)figures 1-3, claims 1,5, 6, 10-12, 17, and 18 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 2-4, 7-9, 13-16, and 19-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species/invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.
- 3. Please note, that the examiner withdrew claims 2-4, 7-9, and 13-15 since the elected species does not contain the elements set forth in those claims, and there is no showing in the figures.

## Specification

4. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because a numerous of corrections to the specification render it difficult to consider the application.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the

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## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 1, 5, 6, 10-12, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - Claims 1, 5, 6, 10, and 11, there is no antecedent basis for "said one or more injury effectors" and "said one or more therapeutic-substance delivery ports".
     The examiner suggests the use of –the at least one injury effector—and --the at least one therapeutic-substance delivery effector--. Moreover, the use of "or more injury effectors" render the claim indefinite because the elected species contain only one injury effector.

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 1, 5, 6, 10-12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (US 5,536,267).

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Edwards discloses a device for treating ischemic tissue having a shaft 12, a control structure 18, at least one injury effector and at least one therapeuticsubstance delivery effector at the distal end of the shaft by means of element 22 and spaced from one another.

9. Claims 1, 5, 6, 10, 11, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hofmann (US 6,241,701).

Hofmann discloses a device for treating ischemic tissue (figs. 1-3, 8-9b, 18a-18b, but better seen in figs. 18a-18b) and having a shaft 1810, a control structure 1812 to be connected to the instrument control, at least one injury effector and at least one therapeutic-substance delivery effector at 1822 at the distal end of the shaft.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to 10. applicant's disclosure. Abele et al, Paddock et al, Giba et al, Ponzi, Mueller et al, Haim et al. Goble et al. Hofmann et al. Ellis et al. Dev et al. and Edwards et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

July 17, 2003

Cris L. Rodriguez

Examiner Art Unit 3763

> MICHAEL J. HAYES PRIMARY EXAMINER